Class 2 Recall
Philips IntelliVue TcG10

See Related Information[22]

Date Posted	January 16, 2015
Recall Status[1]	Open
Recall Number	Z-0997-2015
Recall Event ID	69742[23]
Premarket Notification 510(K) Number	K110474[24]
Product Classification	Monitor, Carbon-Dioxide, Cutaneous[25] - **Product Code** LKD[26]
Product	Philips IntelliVue TcG10; Monitor, carbon-dioxide, cutaneous. The IntelliVue TcG10 is a device for the measurement of the transcutaneous O2 and CO2 partial pressure in neonates, pediatrics and adults.
Code Information	Serial Numbers: CH03800507 CH03800508 CH03800509 CH03800510 CH03800559 CH03800560 CH03800573 CH03800574 CH03800575 CH03800576 CH03800577 CH03800578 CH03800579 CH03800580 CH03800633 CH03800634 CH03800637 CH03800638 CH03800642 CH03800676 CH03800678 CH03800685 CH03800687 CH03800688 CH03800690 CH03800692 CH03800693 CH03800694 CH03800695 CH03800696 CH03800697 UK21001105 UK21001111 UK21001123 UK21001134 UK21001144 UK21001154 UK21001162 UK21001164 UK21001166 UK21001185 UK21001188 UK21001189 UK21001194 UK21001212 UK21001213 UK21001215 UK21001216 UK21001230 UK21001237 UK21001245 UK21001247 UK21001257 UK21001287 UK21001294 UK21001298 UK21001299 UK21001313 UK21001318 UK21001319 UK21001332 UK21001348 UK21001363 UK21001366 UK21001371 UK21001384 UK21001386 UK21001399 UK21001401 UK21001405 UK21001425 UK21001436 UK21001437 UK21001461 UK21001468 UK21001469 UK21001479 UK21001480 UK21001556 UK21001557 UK21001577 UK21001579 UK21001662 UK21001770 UK21001841 UK21001979
Recalling Firm/ Manufacturer	Philips Medical Systems, Inc. 3000 Minuteman Rd Andover, Massachusetts 01810-1032
Manufacturer Reason for Recall	Philips has discovered that the Instructions for Use (IFU) for the IntelliVue TcG10 Transcutaneous Gas Measurement Module is missing the contraindication that the device is not to be used on patients under gas anesthesia.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Customers were notified of the recall by letter sent via UPS on November 19, 2014. The Field Safety Notice informs customers of the issue, identifies details of the units affected, gives instructions on actions to be taken by the customer and identifies what action Philips plans to take to remedy the issue. Philips asked customers to do the following: Upon receipt of this notification, ensure that the IntelliVue TcG10 addendum to the Instructions for Use is being reviewed and implemented by all members of your staff who operate the device. Review this information with all staff members who are involved in the operation of the IntelliVue TcG10 modules and need to be aware of the contents of this communication. The addendum should be stored with the IntelliVue TcG10 Instructions for Use. If you need any further information or support concerning this issue, please contact your local Philips representative or call us at 1-800-722-9377.